must be available to the laboratory at the time of testing and available to HHS upon request. The laboratory must assure that the requisition or test authorization includes—

(a) The patient's name or other unique identifier;

(b) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values;

(c) The test(s) to be performed;

(d) The date of specimen collection;

(e) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and

(f) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.1107 Standard; Test records.

The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. These records must identify the personnel performing the testing procedure. Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years. Immunohematology records and transfusion records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). The record system must provide documentation of information specified in §493.1105 (a) through (f) and include—

(a) The patient identification number, accession number, or other unique identification of the specimen;

(b) The date and time of specimen receipt into the laboratory;

(c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and

(d) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s), which are necessary to assure proper identification and accurate reporting of patient test results.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.1109 Standard; Test report.

The laboratory report must be sent promptly to the authorized person, the individual responsible for using the test results or laboratory that initially requested the test. The original report or an exact duplicate of each test report, including final and preliminary report, must be retained by the testing laboratory for a period of at least two years after the date of reporting. Immunohematology reports and transfusion records must be retained by the laboratory for a period of no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). For pathology, test reports must be retained for a period of at least ten years after the date of reporting. This information may be maintained as part of the patient's chart or medical record which must be readily available to the laboratory and to HHS upon request.

(a) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner, and, ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory's control.

(b) The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result and, if applicable, the units of measurement.

(c) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(d) Pertinent ''reference'' or ''normal'' ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.

(e) The results or transcripts of laboratory tests or examinations must be released only to authorized persons or the individual responsible for utilizing the test results.

(f) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test result indicates an imminent life-threatening condition.

(g) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, in accordance with §493.1213, as applicable, the performance specifications of each method used to test patient specimens. In addition, information that may affect the interpretation of test results, such as test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(h) The original report or exact duplicates of test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.1111 Standard; Referral of specimens.

A laboratory must refer specimens for testing only to a laboratory possessing a valid certificate authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity in which the referred test is categorized.

(a) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

(b) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.

(c) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

SOURCE: 57 FR 7163, Feb. 28, 1992, unless otherwise noted.

§493.1201 Condition: General quality control; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

(a) *Applicability of subpart K of this part.* Subpart K is divided into two sections, general quality control and quality control for specialties and subspecialties. The quality control requirements are specified in §§493.1201 through 493.1285 unless—

(1) An alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for general quality control and specialty/subspecialty quality control, and the manufacturer's instructions contain the following statement,

Unless this device is modified by a laboratory, the laboratory's compliance with these quality control instructions will satisfy the applicable requirements of 42 CFR 493.1203(b).

or